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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,123	04/02/2002	Mary Collins	22058-514NATL	5639

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,123	COLLINS ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,28 and 48-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,28 and 48-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 13 July 2004 has been entered in full. Claims 1-22, 24-27 and 29-47 were cancelled. New claims 48-67 were added. Claims 23, 28 and 48-67 are under examination.

The Figure 2 drawing submitted 26 August 2004 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 23, 28, 31, 44 and 47 under 35 U.S.C. 112, second paragraph, as set forth at page 3 of the previous Office Action (14 January 2004) is *withdrawn* in view of the amendment (13 July 2004).

The rejection to claims 45-47 under 35 U.S.C. 112, first paragraph, enablement as set forth at pages 9-10 of the previous Office Action (14 January 2004) is *withdrawn* in view of the amendment (13 July 2004).

The rejection to claims 39-46 under 35 U.S.C. 112, first paragraph, written description as set forth at pages 10-12 of the previous Office Action (14 January 2004) is *withdrawn* in view of the amendment (13 July 2004).

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 23, 28, 48-67 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement. The basis for this rejection is set forth at pages 3-6 of the previous Office Action (14 January 2004).

Applicant states that claim 23 as amended is drawn to a method of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject by administering a polypeptide encoded by a polynucleotide that hybridizes at high stringency to the complement of the portion of SEQ ID NO:3 that encodes about from about amino acid 26 to about amino acid 341 of SEQ ID NO:4. Applicant maintains that amino acids 26 to 341 correspond to the extracellular portion of the human IL-13 receptor disclosed in the specification.

Applicant's arguments have been fully considered but are not deemed persuasive. In the absence of a recitation of clear hybridization conditions (claims 23 and 28), the nucleic acid sequence will hybridize with unrelated DNA sequences, corresponding sequences from other species, mutated sequences, allelic variants, splice variants and so forth. The instant claims still encompass administering variants. There is no description of polypeptides encoded by polynucleotide variants, mutated sequences, fragments, etc that exist, while still maintaining function (inhibition of IL-13 to the IL-13 receptor). As was stated in the previous Office Action, the specification provides little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (deletions), and the nature and extent of

changes that can be made in these positions. The specification provides no working example of any fragment or mutant sequences which would be within the instant claims. As is well recognized in the art, any modification (even a "conservative" substitution) to a critical structural region of a protein is likely to significantly alter its functional properties. It is in no way predictable that disclosed fragment sequences would afford a protein having activity comparable to the one disclosed.

The specification is enabling for ".....administering a polypeptide encoded by a polynucleotide that hybridizes to the complement of the portion of SEQ ID NO:3 that encodes about from about amino acid 26 to about amino acid 341 of SEQ ID NO:4 **(with a recitation of clear hybridization conditions as originally filed in the specification)**" but not enabling for the instant claims, which lack clear hybridization conditions.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claims 28, 56-67 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement. The basis for this rejection is set forth at pages 6-8 of the previous Office Action (14 January 2004).

Applicant states that claim 28 is now directed to specify IL-13 related conditions including an allergic condition, atopy or asthma. Applicants submit that the artisan can readily practice the full scope of the invention now claimed.

Applicant's arguments have been fully considered and are deemed partly persuasive. The Examiner agrees with Applicant that an effect was seen with the airway hyper responsiveness (AHR) murine model (Example 6). The Examiner stated in the previous Office Action, that the specification was enabling for a method of treating allergen-induced airway hyperresponsiveness in a mammalian subject. However, while the AHR murine model may encompass asthma, it would not include "any" allergic condition or allergic reaction. The scope of the instant claims exceeds the scope of the enabling disclosure. The Examiner has provided a definition of atopy from the On-line Medical Dictionary. Atopy is defined as an allergic reaction with strong family tendencies.

Therefore, the specification is enabling for treating an IL-13 related condition in a mammalian subject, wherein the IL-13 related condition is asthma, but not enabling for allergic conditions or atopy.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description, New Matter

Claims 23, 28 and 48-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed, "polypeptide encoded by a polynucleotide that hybridizes at high stringency....." (claims 23 and 28) and "wherein said mammalian subject is a human" (claim 54). Applicant's amendment, filed 13 July 2004 , asserts that no new matter has been added and directs support to page 4, lines 21-26, page 9, lines 20-23 and the original claims for the written description for the above-mentioned "limitations". However, the exact wording or connotation of the instant claims is not readily apparent from said sections.

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

Claims 23, 28 and 48-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification provides adequate written description for SEQ ID NOs:3 and 4, but not variants. The instant claims are directed to a polypeptide encoded by a polynucleotide that hybridizes at high stringency to the complement of the portion of SEQ ID NO:3, that encodes about from about amino acid 26 to about amino acid 341 of SEQ ID NO:4, and wherein said IL-13 related condition is selected from the group consisting of an allergic condition, atopy and asthma.

In the absence of a recitation of clear hybridization conditions, the nucleic acid sequence will hybridize with unrelated DNA sequences, corresponding sequences from other species, mutated sequences, allelic variants, splice variants and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of SEQ ID Nos 3 and 4, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Therefore, only SEQ ID NOs:3 and 4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 23 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite, "....polypeptide encoded by a polynucleotide that hybridizes at high stringency.....". Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of A X SSC and B % SDS at COC"), the claims fail to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods.

Claim Objections

Claim 23 objected to because of the following informalities: the instant claim recites "the method comprising administering **a a** polypeptide". Appropriate correction is required.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
10/19/04

ELIZABETH KEMMERER
PRIMARY EXAMINER